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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,037	03/11/2004	Jeffrey Robbins	CHM02-GN054	5033

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,037	ROBBINS, JEFFREY	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to an animal cell stably transformed with an expression cassette comprising a promoter having the nucleotide sequence of SEQ ID No. 1 or 2, nucleotide sequence at least 90% identical to SEQ ID No. 1 or 2, or a nucleotide sequence comprising at least 50 contiguous nucleotides of SEQ ID No. 1 or 2, and a heterologous nucleotide sequence operably linked to said promoter, classified in class 424, subclass 93.2.

II. Claims 10-26 and 35-39, drawn to a transgenic rabbit or animal comprising in its genome at least one stably incorporated expression cassette comprising a promoter having the nucleotide sequence of SEQ ID No. 1 or 2, nucleotide sequence at least 90% identical to SEQ ID No. 1 or 2, or a nucleotide sequence comprising at least 50 contiguous nucleotides of SEQ ID No. 1 or 2, and a heterologous nucleotide sequence operably linked to said promoter, classified in class 800, subclass 13.

III. Claims 27-33 and 40-42, drawn to a method of altering expression of a heterologous nucleotide sequence in an animal comprising providing a transgenic animal comprising in its genome at least one stably incorporated expression cassette comprising a promoter having the nucleotide sequence of SEQ ID No. 1 or 2, nucleotide sequence at least 90% identical to SEQ ID No. 1 or 2, or a nucleotide sequence comprising at least 50 contiguous nucleotides of SEQ ID No. 1 or 2, and a heterologous nucleotide sequence operably linked to said promoter, and determining expression levels of said heterologous nucleotide sequence in

said animal, and a kit comprising a transgenic rabbit for performing said method, classified in classes 800 and 435, subclasses 3 and 810, respectively.

IV. Claims 34 and 44-49, drawn to a method of identifying anti-cardiopathic compounds by using first and second transgenic rabbits whose genomes comprise an expression cassette comprising a promoter having the nucleotide sequence of SEQ ID No. 1 or 2, nucleotide sequence at least 90% identical to SEQ ID No. 1 or 2, or a nucleotide sequence comprising at least 50 contiguous nucleotides of SEQ ID No. 1 or 2, and a heterologous nucleotide sequence operably linked to said promoter, and monitoring the rabbit for a modulation of a cardiopathic phenotype, classified in classes 800 and 435, subclasses 3 and 810, respectively.

V. Claim 43, drawn to a kit for performing a method of altering expression of a heterologous nucleotide sequence in an animal, said kit comprising at least one expression cassette comprising a promoter having the nucleotide sequence of SEQ ID No. 1 or 2, nucleotide sequence at least 90% identical to SEQ ID No. 1 or 2, or a nucleotide sequence comprising at least 50 contiguous nucleotides of SEQ ID No. 1 or 2, classified in classes 435 and 536, subclasses 810 and 320.1, and 24.1, respectively.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are distinct from each other because they are drawn to compositions having different chemical structures, physical properties and biological functions, and requiring separate search: an animal cell vs. a transgenic rabbit or a transgenic animal. Since the classification for each group is different, the search for each group would not be coextensive.

Thus, they are not obvious variants and are patentably distinct from each other. Similarly, groups I and III or groups I and IV are patentably distinct from each other for the same reason.

Group I and V are distinct from each other because they are drawn to different scientific consideration: an animal cell transformed with an expression cassette comprising a promoter and a heterologous nucleotide sequence vs. a kit comprising at least one expression cassette comprising a promoter for performing a method of altering expression of a heterologous nucleotide sequence. They have different chemical structures and biological functions. The animal cells can be used for producing a recombinant protein encoded by the heterologous nucleotide sequence. However, the expression cassette comprising a promoter in the kit can be used as a probe for DNA detection and said kit is used for a method of altering expression. They have different classifications and require separate search. Thus, they are not obvious variants and are patentably distinct from each other.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the transgenic rabbit or animal in group II can be used for producing a recombinant protein instead of being used for a method of altering expression of a heterologous nucleotide sequence in an animal. Since the classification for each group is different, the search for each group would not be coextensive. Thus, they are not obvious variants and are patentably distinct from each other.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the transgenic rabbit or animal in group II can be used for producing a recombinant protein instead of being used for a method of identifying anti-cardiopathic compounds. Since the classification for each group is different, the search for each group would not be coextensive. Thus, they are not obvious variants and are patentably distinct from each other.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are a method of altering expression of a heterologous nucleotide sequence in an animal and a method of identifying anti-cardiopathic compounds. They differ in objectives, method steps, reagents and dosages used, schedules used, response variables, and criteria of success. A search for group III does not require a search for group IV and vice versa. Thus, groups III and IV are patentably distinct from each other.

Groups II-IV and group V are distinct from each other because they are drawn to compositions having different chemical structures, physical properties and biological functions, and requiring separate search: a transgenic rabbit or a transgenic animal or a method of using it vs. a kit comprising an expression cassette. They have different classifications and require

separate search. The search for those groups would not be coextensive. Thus, they are not obvious variants and are patentably distinct from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER